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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,182	02/12/2001	John N. Vournakis	7867-022-999	2779

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EXAMINER

LEWIS, PATRICK T

ART UNIT PAPER NUMBER

1623

11

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/781,182

Applicant(s)

VOURNAKIS ET AL.

Examiner

Patrick T. Lewis

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-17, 24-28 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-17, 24-28 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Objections/Rejections Set For the in Office Action dated August 8, 2002

1. Claims 1-5, 11-17, 24-28, 32-34, and 36-38 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for achieving at least a transient, localized, modulation of vascular structure and/or function; a method of treating a patient having a vascular disorder; and compositions comprising semi-crystalline poly- β -1 \rightarrow 4 N-acetylglucosamine polymers wherein the polymer comprises 50 to about 150,000 monosaccharide units, does not reasonably provide enablement for a method for achieving at least a transient, localized, modulation of vascular structure and/or function; a method of treating a patient having a vascular disorder; and compositions comprising semi-crystalline poly- β -1 \rightarrow 4 N-acetylglucosamine polymers of any molecular weight or size.
2. Claims 1-38 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1-17, 24-28, and 32-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vournakis et al. US 5,635,493 (Vournakis) in view of Barton et al. *Curr. Opin. Nephrol. Hypertens.* (1999), vol. 8, pages 549-556 (Barton) and Pearson *Lupus* (2000), vol. 9, pages 183-188 (Pearson).
4. Claims 18-23, 29-31, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vournakis et al. US 5,635,493 (Vournakis).

Applicant's Response dated February 10, 2003

5. In the Response filed February 10, 2003, claims 1, 18-23, 29-31, and 35-38 were canceled. Claims 2, 4-7, 10-14, 17, 24, and 26-28 were amended.

6. Applicant presented arguments directed to the rejection of claims 1-5, 11-17, 24-28, 32-34, and 36-38 under 35 U.S.C. 112, first paragraph; the rejection of claims 1-38 under 35 U.S.C. 112, second paragraph; and the rejection of claims 1-17, 24-28, and 32-34 under 35 U.S.C. 103(a). Claims 2-17, 24-28, and 32-34 are pending. An action on the merits of claims 2-17, 24-28, and 32-34 is contained herein below.

7. The rejection of claims 1-5, 11-17, 24-28, 32-34, and 36-38 under 35 U.S.C. 112, first paragraph, has been rendered moot in view of the amendment dated February 10, 2003.

8. The rejection of claims 1-38 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of the amendment dated February 10, 2003.

9. The rejection of claims 1, 18-23, 29-31, and 35-38 under 35 U.S.C § 103(a), has been rendered moot in view of the amendment dated February 10, 2003.

10. The rejection of claims 2-17, 24-28, and 32-34 under 35 U.S.C § 103(a), is maintained for the reasons of record set forth in the Office Action dated August 8, 2002.

Response to Arguments

11. Applicant's arguments filed February 10, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) the examiner has failed to set forth motivation to combine references; 2) the examiner has failed to establish a reasonable expectation of success; and 3) the examiner has used hindsight reasoning. In response to applicant's assertion that the examiner has failed to establish a *prima facie* case of obviousness, the examiner respectfully disagrees.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding the lack of motivation, the examiner notes that obviousness may be based on the motivation to combine prior art references where the motivation to combine is either a teaching or suggestion in an individual reference of the proposed combination or in the prior art references as a whole, or in the knowledge generally available to those skilled in the art. In the instant case, the Vournakis et al. reference teaches the use of p-GlcNAc based materials to promote hemostasis [the arrest of bleeding] (column 35, lines 38-52). The p-GlcNAc material, when applied directly to bleeding surfaces, arrests bleeding by providing a mechanical matrix that promotes clotting. This reduces the amount of blood loss, protects the forming clot and facilitates

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the clotting process. Indeed, Vournakis teaches the administration of p-GlcNAc to a population in need of a transient, localized, modulation of vascular structure and/or function. While Vournakis was silent as to stimulation of endothelin-1 release and vasoconstriction, the instant claims merely recite newly discovered results ---stimulation of endothelin-1 release and vasoconstriction--- of a known method to the same use. The claimed process is not directed to a new use, it is the same use and it consists of the same method as described by Vournakis. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.

Additionally, Pearson teaches that normal endothelial cell function is critical for all aspects of vascular homeostasis (page 183, column 1). Pearson further teaches that the active metabolism of these cells is necessary for the continuous adjustment of vascular tone, and hence the control of blood pressure; for the physiological regulation of leukocyte traffic from blood tissues; and for the maintenance of an antithrombotic and anticoagulant balance in flowing blood (page 183, column 1). Barton teaches that the endothelin system has been implicated in the pathogenesis of arterial hypertension and renal disorders (page 549, column 1). Barton also teaches that endothelin-1 is the predominant isoform of the endothelin peptide family and regulates vasoconstriction and cell proliferation in tissues both within and outside the cardiovascular system.

Regarding the assertion that there is no reasonable expectation of success, the examiner respectfully disagrees. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are

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inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. Thus, one of ordinary skill in the art at the time of the invention would have a reasonable expectation of success in achieving stimulation of endothelin-1 release and vasoconstriction by topically administering p-GlcNAc to a population in need of a transient, localized, modulation of vascular structure and/or function.

In the absence of some proof of a secondary nature to obviate the rejection as set forth in the Office Action dated August 8, 2002, or of some specific limitations which would tip the scale of patentability in the favor of the instantly claimed invention, it would have been obvious to one of ordinary skill in this art at the time the invention was made to administer p-GlcNAc to accomplish the modulation of vascular structure or function using the method described by Vournakis in view Barton and Pearson, which would also inherently facilitate the release of endothelin-1 and vasoconstriction. Indeed, this combination of references establishes a prima facie case of obviousness which is maintained for the reasons set forth herein.

Conclusion

12. Claims 2-17, 24-28, and 32-34 are pending. Claims 2-17, 24-28, and 32-34 are rejected. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

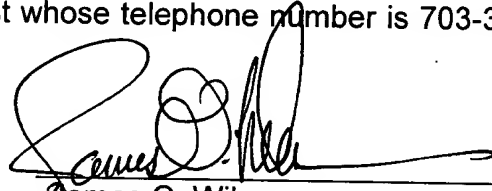
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
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James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
May 1, 2003